

**INSTRUCTIONS FOR COMPLETING AN
APPLICATION FOR LICENSURE OF A CLINICAL LABORATORY
(UNDER THE PROVISIONS OF N.J.S.A. 45:9-42.26 ET SEQ.)**

NOTICE TO ALL APPLICANTS FOR A CLINICAL LABORATORY LICENSE:

The signed and notarized application for licensure of a Clinical Laboratory, under the provisions of N.J.S.A. 45:9-42.26 et seq., and all requested attachments, must be completed in full and returned to the above address with the appropriate fee. Fees are non-refundable and incomplete applications will not be processed.

Checks or money orders should be made payable to the New Jersey Department of Health and Senior Services.

INITIAL LICENSURE (Check appropriate box on top of page one):

Application for an initial license to conduct a clinical laboratory shall be made on forms provided for that purpose by the New Jersey Department of Health and Senior Services.

Each license to operate a clinical laboratory will indicate those laboratory specialties or subspecialties which the laboratory will be authorized to performed.

A license issued under these regulations IS NOT TRANSFERABLE.

A new license shall be obtained whenever the name, location, ownership or director of a clinical laboratory is changed. **The department must be notified by certified mail within fourteen days of such changes.**

The license shall be conspicuously displayed by the licensee on the laboratory premises.

ANNUAL RENEWAL OF LICENSURE (Check appropriate box on top of page one):

All clinical laboratory licenses shall be issued on or before January 1 of each calendar year and shall expire on December 31 of each calendar year.

The Department of Health and Senior Services will provide applications for licensure renewal on or before October 1 of each year to be properly completed and returned to the Department, together with the appropriate licensure renewal fee, **on or before the succeeding November 1.**

Important: Please type or print with ballpoint pen when completing application.

Special Note: If there are two applications in this packet, (i.e., an application for a Clinical Laboratory License and an Application for Selection of an Approved Proficiency Testing Program), then the applications are to be submitted with separate checks (i.e., one for licensure and one for proficiency testing) and returned to this office at the same time.

LICENSURE FEES

Initial and annual renewal fees shall be identical and are prescribed by the following table. Fees noted are for each specialty. Complete and return this form with your application.

| Specialty | Staff Categories Based on the Total Number of Employees of Entire Laboratory * | | | | |
|--|---|----------------|--------------|---------------------|---------------------|
| | I 1-9 | II 10-29 | III 30-49 | IV 50-89 | V 90 or More |
| Urinalysis | \$100 | \$125 | \$150 | \$175 | \$200 |
| Bacteriology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Mycobacteriology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Parasitology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Mycology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Virology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Diagnostic Immunology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Hematology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Immunohematology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Routine Chemistry | \$100 | \$125 | \$150 | \$175 | \$200 |
| Endocrinology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Toxicology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Cytology | \$100 | \$125 | \$150 | \$175 | \$200 |
| Cytogenetics and/or Tissue Typing | \$100 | \$125 | \$150 | \$175 | \$200 |
| Collection Station Only ** | / / / / / / / / / / | \$100 per Site | | / / / / / / / / / / | / / / / / / / / / / |
| Collection Station Performing Waived Tests Only | / / / / / / / / / / | \$150 per Site | | / / / / / / / / / / | / / / / / / / / / / |

* Exclusive of director, co-director, students of approved schools of medical technology, clerical and maintenance employees. Part-time employees are to be included, pro-rated to full-time equivalents. Minimum fees are applicable to "one-man" laboratories (i.e., labs in which all testing is done by the director).

** Laboratories that perform testing in any specialty or subspecialty are not required to pay a collection station fee.

NOTE: Laboratories submitting renewal applications after December 31st are required to pay an additional \$50 per application.

Laboratories requiring a replacement license due to a change of address must submit a \$50 fee per change.

FEE CALCULATIONS

- | | |
|--|--|
| A. Number of Full-Time Employees | |
| B. Total Number of Hours of Part-Time Employees | |
| C. Part Time Employee Hours Pro-Rated to Full Time = $\frac{(B)}{40}$ (Round off to nearest whole number) | |
| D. Total Number of Employees [(A) + (C) = (D)] | |
| E. Staff Category Appropriate to (D) Above (I, II, III, etc.) | |
| F. Fee Per Specialty as Indicated Under the Appropriate Category in (E) | |
| G. Number of Licensed Specialties | |
| H. Total Fee (Fee Indicated Per Specialty in (F) Multiplied by the Number of Licensed Specialties in (G)) | |

**New Jersey Department of Health and Senior Services
Clinical Laboratory Improvement Service
PO Box 361
Trenton, NJ 08625-0361**

www.state.nj.us/health/phel/clis.htm

APPLICATION FOR A CLINICAL LABORATORY LICENSE

| | | | | |
|--|---------------------------|---------------|--|------------|
| Type of Application <input type="checkbox"/> Initial <input type="checkbox"/> Renewal | FOR STATE USE ONLY | | | |
| | Date Mailed | Date Received | <input type="checkbox"/> Approved <input type="checkbox"/> Other <input type="checkbox"/> Denied | |
| | Received By | Check Number | Amount | Check Date |

| | |
|---|---------------------------------------|
| Name and Address of Laboratory | Name of Person Completing Application |
| | Telephone Number () |
| CLIS ID Number | Fax Number () |
| CLIA '88 Certificate Number <input type="checkbox"/> Check here if not yet assigned | E-Mail Address |
| Normal Hours of Operation [Indicate specific hours <u>EACH</u> day]: Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____ | |
| Give, if applicable the identification of all other associated laboratory sites ("Parent" laboratory, subsidiary or satellite laboratories, collection stations). Complete a separate application for each site listed and specify mailing address for receipt of proficiency test specimens, if different from above. Also list, if applicable, out-of-state parent laboratory. Parent Lab: _____ Address: _____ Name: _____ Address: _____ Name: _____ Address: _____ Name: _____ Address: _____ | |
| Type of Laboratory (Check only one appropriate type) A. <input type="checkbox"/> Hospital <input type="checkbox"/> Hospital Associated (Off Site) <input type="checkbox"/> Independent <input type="checkbox"/> Physician Office <input type="checkbox"/> Ambulatory Surgical Center <input type="checkbox"/> Health Care Related Clinics <input type="checkbox"/> Urgent Care Services <input type="checkbox"/> Industrial Medicine Department/Employee Health Offices <input type="checkbox"/> Mobile Testing <input type="checkbox"/> School <input type="checkbox"/> Other, Specify: _____ B. <input type="checkbox"/> On-Site Testing <input type="checkbox"/> Collection Only <input type="checkbox"/> Collect and Perform New Jersey Waived Tests Only | |

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

| OWNERSHIP INFORMATION | |
|--|--|
| Name of Authorized Agent/Owner | Telephone Number () |
| Address | |
| Type of Ownership <input type="checkbox"/> Individual <input type="checkbox"/> Partnership * <input type="checkbox"/> Corporation * <input type="checkbox"/> Government - Type <input type="checkbox"/> State <input type="checkbox"/> County <input type="checkbox"/> Municipal | |
| Name of Owner/Corporate Director | <input type="checkbox"/> Owner <input type="checkbox"/> Corporate Director |
| Address | |
| Name of Owner/Corporate Director | <input type="checkbox"/> Owner <input type="checkbox"/> Corporate Director |
| Address | |
| Name of Owner/Corporate Director | <input type="checkbox"/> Owner <input type="checkbox"/> Corporate Director |
| Address | |
| Name of Owner/Corporate Director | <input type="checkbox"/> Owner <input type="checkbox"/> Corporate Director |
| Address | |
| Name of Owner/Corporate Director | <input type="checkbox"/> Owner <input type="checkbox"/> Corporate Director |
| Address | |
| Name of Owner/Corporate Director | <input type="checkbox"/> Owner <input type="checkbox"/> Corporate Director |
| Address | |
| Name of Owner/Corporate Director | <input type="checkbox"/> Owner <input type="checkbox"/> Corporate Director |
| Address | |

* Attach list of officers and the corporate structure of ownership.

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

| INFORMATION ON LABORATORY DIRECTOR | | | | | | | | | | | | | |
|--|---|--------------------------------------|---|-------------------------------------|-----------------------------------|-------------------------------------|----------------------------------|-----------------------------|-----------------------------|------------------------------|--------------------------------|-----------------------------------|--|
| Name of Laboratory Director | Telephone Number () | | | | | | | | | | | | |
| Address | | | | | | | | | | | | | |
| <p>Is Director licensed as a Bioanalytical Laboratory Director in New Jersey?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, give Bioanalytical Laboratory Director's License Number: _____ Expiration Date: _____</p> <p>Director's Qualifications:</p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Pathologist</td> <td><input type="checkbox"/> CP</td> <td><input type="checkbox"/> AP</td> <td><input type="checkbox"/> DDS</td> <td><input type="checkbox"/> Ph.D.</td> <td><input type="checkbox"/> Masters</td> </tr> <tr> <td><input type="checkbox"/> MD</td> <td><input type="checkbox"/> DO</td> <td><input type="checkbox"/> DVM</td> <td><input type="checkbox"/> D.Sc.</td> <td><input type="checkbox"/> Bachelor</td> <td></td> </tr> </table> <p><input type="checkbox"/> Other-Specify: _____</p> <p>Director's Time on Premises (Indicate specific hours each day, e.g., 1:30 PM - 3:00 PM):</p> <p><input type="checkbox"/> Full Time <input type="checkbox"/> Part Time</p> <p>Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____</p> | | <input type="checkbox"/> Pathologist | <input type="checkbox"/> CP | <input type="checkbox"/> AP | <input type="checkbox"/> DDS | <input type="checkbox"/> Ph.D. | <input type="checkbox"/> Masters | <input type="checkbox"/> MD | <input type="checkbox"/> DO | <input type="checkbox"/> DVM | <input type="checkbox"/> D.Sc. | <input type="checkbox"/> Bachelor | |
| <input type="checkbox"/> Pathologist | <input type="checkbox"/> CP | <input type="checkbox"/> AP | <input type="checkbox"/> DDS | <input type="checkbox"/> Ph.D. | <input type="checkbox"/> Masters | | | | | | | | |
| <input type="checkbox"/> MD | <input type="checkbox"/> DO | <input type="checkbox"/> DVM | <input type="checkbox"/> D.Sc. | <input type="checkbox"/> Bachelor | | | | | | | | | |
| <p>Does Director serve as Director or Co-Director for laboratories at other locations?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If yes, give names and addresses of other laboratories, whether or not located in New Jersey. Indicate specific hours for each day on premises (e.g., 1:30 PM - 3:00 PM) (Attach additional pages, if necessary):</p> <p>Name: _____</p> <p>Address: _____</p> <p>Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____</p> <p>Name: _____</p> <p>Address: _____</p> <p>Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____</p> <p>Name: _____</p> <p>Address: _____</p> <p>Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____</p> | | | | | | | | | | | | | |
| <p>Other employment of Director (include name of facility, location, title and daily hours):</p> <table style="width: 100%; border: none;"> <tr> <td><input type="checkbox"/> Hospital</td> <td><input type="checkbox"/> Private Practice</td> <td><input type="checkbox"/> Government</td> <td><input type="checkbox"/> Teaching</td> <td><input type="checkbox"/> Consulting</td> </tr> </table> <p><input type="checkbox"/> None <input type="checkbox"/> Other-Specify: _____</p> <p>Name: _____</p> <p>Address: _____</p> <p>Title: _____</p> <p>Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____</p> <p>Name: _____</p> <p>Address: _____</p> <p>Title: _____</p> <p>Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____</p> <p>Name: _____</p> <p>Address: _____</p> <p>Title: _____</p> <p>Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____</p> | | <input type="checkbox"/> Hospital | <input type="checkbox"/> Private Practice | <input type="checkbox"/> Government | <input type="checkbox"/> Teaching | <input type="checkbox"/> Consulting | | | | | | | |
| <input type="checkbox"/> Hospital | <input type="checkbox"/> Private Practice | <input type="checkbox"/> Government | <input type="checkbox"/> Teaching | <input type="checkbox"/> Consulting | | | | | | | | | |

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

INFORMATION ON LABORATORY CO-DIRECTOR

Name of Laboratory Co-Director

Telephone Number

()

Address

Is Co-Director licensed as a Bioanalytical Laboratory Director in New Jersey?

☐ Yes ☐ No

If yes, give Bioanalytical Laboratory Director's License Number: _____

Co-Director's Qualifications:

☐ Pathologist ☐ CP ☐ AP ☐ DDS ☐ Ph.D. ☐ Masters
☐ MD ☐ DO ☐ DVM ☐ D.Sc. ☐ Bachelor

☐ Other-Specify: _____

Co-Director's Time on Premises (Indicate specific hours each day, e.g., 1:30 PM - 3:00 PM):

☐ Full Time ☐ Part Time

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Does Co-Director serve as Director or Co-Director for laboratories at other locations?

☐ Yes ☐ No

If yes, give names and addresses of other laboratories, whether or not located in New Jersey.

Indicate specific hours for each day on premises (e.g., 1:30 PM - 3:00 PM) (Attach additional pages, if necessary):

Name: _____

Address: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Name: _____

Address: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Name: _____

Address: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Other employment of Co-Director (include name of facility, location, title and daily hours):

☐ Hospital ☐ Private Practice ☐ Government ☐ Teaching ☐ Consulting
☐ None ☐ Other-Specify: _____

Name: _____

Address: _____

Title: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Name: _____

Address: _____

Title: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

Name: _____

Address: _____

Title: _____

Mon _____ Tue _____ Wed _____ Thu _____ Fri _____ Sat _____ Sun _____

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

LABORATORY PERSONNEL

List all personnel who are serving as a director, co-director, general supervisor, technical supervisor, cytology general supervisor, technologist, cytotechnologist, technician, trainee, technical aide, or phlebotomist in the laboratory. Use the codes below to indicate the function of each employee.

[illegible]

Codes: D/CO - Director/Co-Director
GS - General Supervisor
TS - Technical Supervisor

CT/GS - Cytology General Supervisor
T - Technologist
CT - Cytotechnologist

TN - Technician
A - Laboratory Assistant
P - Phlebotomist Only

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

LABORATORY PERSONNEL, CONTINUED

List all personnel who are serving as a director, co-director, general supervisor, technical supervisor, cytology general supervisor, technologist, cytotechnologist, technician, trainee, technical aide, or phlebotomist in the laboratory. Use the codes below to indicate the function of each employee.

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APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

LABORATORY PERSONNEL, CONTINUED

List all personnel who are serving as a director, co-director, general supervisor, technical supervisor, cytology general supervisor, technologist, cytotechnologist, technician, trainee, technical aide, or phlebotomist in the laboratory. Use the codes below to indicate the function of each employee.

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CT/GS - Cytology General Supervisor
T - Technologist
CT - Cytotechnologist

TN - Technician
A - Laboratory Assistant
P - Phlebotomist Only

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

LABORATORY SPECIALTIES / SUBSPECIALTIES

Check the column (X) for the specialties/subspecialties in which your laboratory is seeking licensure. Also, please check boxes for any applicable limitations.

DO NOT REQUEST LICENSURE IF ALL SPECIMENS IN A SPECIALTY ARE REFERRED ELSEWHERE.

| STATE USE ONLY | X | Specialty / Subspecialty | Annual Number of | | Number of Specimens or Tests Referred |
|----------------------|-----|--|---------------------|--------------------|---|
| | | | Specimens Tested | Tests Performed | |
| | | URINALYSIS | ////////// | | |
| | | BACTERIOLOGY | | ////////// | |
| | | Initiation of Cultures Only | | ////////// | |
| | | Initiation of Cultures - Growth/No Growth | | ////////// | |
| | | Gram Stains-Routine | | ////////// | |
| | | G.C. Smears Only | | ////////// | |
| | | Urine Culture (Bacterial ID) | | ////////// | |
| | | Colony Count Screen Only | | ////////// | |
| | | Throat Culture | | ////////// | |
| | | Throat - DAT (Direct Antigen Test) | | ////////// | |
| | | G.C. Cultures | | ////////// | |
| | | Yeast Screen (not definitive, e.g., germ tube) | | ////////// | |
| | | Vaginal Wet Mounts | | ////////// | |
| | | Antimicrobial Susceptibility Testing | | ////////// | |
| | | OB-GYN DAT (Group B Strep) | | ////////// | |
| | | MYCOBACTERIOLOGY * | | ////////// | |
| | | Class I-AFB Smears Only | | ////////// | |
| | | Class II-AFB Smears & Initiation of Cultures | | ////////// | |
| | | Class III-Complete ID of TB Complex Only | | ////////// | |
| | | Class IV-Complete ID of Other Species | | ////////// | |
| | | MYCOLOGY | | ////////// | |
| | | Class I - Initiation and/or Screen Only ** | | ////////// | |
| | | Class II - Initiation of Cultures Only | | ////////// | |
| | | Class III - Complete ID of Yeast Only | | ////////// | |
| | | Class IV - Complete ID, Other than Yeast | | ////////// | |
| | | PARASITOLOGY | | ////////// | |
| | | Pinworms Only | | ////////// | |
| | | Non-Definitive Screen (Absence/Presence | | ////////// | |
| | | VIROLOGY (VIRAL ANTIGENS) | ////////// | | |
| | /// | DIAGNOSTIC IMMUNOLOGY | ////////// | ////////// | ////////// |
| | | SYPHILIS SEROLOGY | ////////// | | |
| | | GENERAL IMMUNOLOGY | ////////// | | |
| | | CHEMISTRY | ////////// | | |
| | | Blood Gases | ////////// | | |
| | | ENDOCRINOLOGY | ////////// | | |
| | | TOXICOLOGY | ////////// | | |
| | | Blood Lead | ////////// | | |
| | | Erythrocyte Protoporphyrin | ////////// | | |
| | | Metallic Poisoning Only (Mercury, etc.) | ////////// | | |
| | | Therapeutic Drug Levels (Lithium, etc.) | ////////// | | |
| | | Drug Overdose (Alcohol, Barbiturates, etc.) | ////////// | | |
| | | Drug Abuse (Opiates, Amphetamines, etc.) | ////////// | | |
| | /// | IMMUNOHEMATOLOGY | ////////// | ////////// | ////////// |
| | | ABO Group and D (Rho) Typing | ////////// | | |
| | | Unexpected Antibody Detection | ////////// | | |
| | | Compatibility Testing | ////////// | | |
| | | Antibody Identification | ////////// | | |
| | | HEMATOLOGY AND COAGULATION | ////////// | | |

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

| LABORATORY SPECIALTIES / SUBSPECIALTIES | | | | | |
|---|---|---|---------------------|--------------------|---|
| STATE USE ONLY | X | Specialty / Subspecialty | Annual Number of | | Number of Specimens or Tests Referred |
| | | | Specimens Tested | Tests Performed | |
| | | CYTOLOGY (PAP SMEAR/THIN LAYER PREP) | | ////////// | |
| | | Cytogenetics | | ////////// | |
| | | Molecular Genetics | ////////// | | |
| | | Biochemical Genetics | ////////// | | |
| | | Histocompatibility | | ////////// | |
| | | Histopathology | | ////////// | |
| | | Oral Pathology | | ////////// | |
| | | Radiobioassay | | ////////// | |
| | | COLLECTION STATION ONLY | ////////// | ////////// | |

* Licensure approval contingent upon availability of a microbiological safety cabinet which meets the standards of NSF-49.

** Not definitive; For Dermatophytes (hair, skin & nails) Only; (e.g., KOH, Dermatophyte Media)

Annual total number of patients accessioned: _____

List below all Laboratories to which work not performed on the premises is referred:

Name: _____

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

Name: _____

Address: _____

PROCEDURES PERFORMED

The information requested below will not affect specialty/subspecialty fees.

A. Do you perform culture procedures for the following types of specimens?

MICROBIOLOGY

- | | YES | NO |
|-----------------------|--------------------------|--------------------------|
| 1. Abscess/Wound | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Blood | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Anaerobic Cultures | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Ear | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Eye | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Stool/Rectal Swab | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Body Fluids: | | |
| a. Cerebrospinal | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Other, Specify: | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> |

- | | YES | NO |
|---------------------------------|--------------------------|--------------------------|
| 8. Respiratory Tract: | | |
| a. Nose | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Sputum | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Throat | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Urine | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. GC Smears | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. GC Cultures | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Gram Stains (Other Than GC) | <input type="checkbox"/> | <input type="checkbox"/> |

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

PROCEDURES PERFORMED

B. List bacteria identified by the applicant lab using:

1. Rapid antigen detection tests, enzyme immunoassays or immunofluorescence:

2. Other (PCR, Nucleic Acid Probe, etc.)

3. If your protocol calls for less than complete identification (e.g. genus only) for all or some type of specimens or organisms, please indicate the limitations:

C. List viruses, rickettsias and spirochetes identified by the applicant lab using:

1. Culture techniques or direct immunofluorescence:

2. Enzyme immunoassay or latex agglutination:

3. Other (PCR, Nucleic Acid Probe, etc.)

D. Check all parasites that you identify completely:

☐ Protozoa

☐ Coccidia

☐ Helminths

☐ Blood and Tissue Parasites

1. Indicate any parasites which you do not identify or for which you perform a limited identification (e.g., Plasmodium species, etc.):

E. If your mycology protocol calls for less than complete identification (e.g., genus only) for all or some types of specimens or organisms, please indicate the limitations:

F. If the testing site laboratory's protocol for Class IV Mycobacteriology (i.e., complete ID of all species) does not include the identification of ALL species, please indicate the limitations:

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

PROCEDURES PERFORMED, CONTINUED

G. At what biosafety level does your laboratory routinely function?

- ☐ Level 1
 ☐ Level 2
 ☐ Level 3
 ☐ Level 4

Would your facility be willing to participate with the Department of Health and Senior Services in the National Laboratory Response Network as a Level A* Statewide Bioterrorism Response Laboratory?

- ☐ Yes
 ☐ No

Comments: _____

*Level A: Biosafety Level 2 Laboratory with a Certified Class II Biological Safety Cabinet.

H. In accordance with N.J.A.C. 8:44-2.12, clinical laboratories where live pathogenic microorganisms are handled, cultivated or kept are required to notify the Department of Health and Senior Services. Please indicate from the following list all live viruses, bacteria, rickettsiae, fungi, and toxins maintained by this laboratory site:

VIRUSES

- ☐ Crimean-Congo haemorrhagic fever virus
☐ Eastern Equine Encephalitis virus
☐ Ebola viruses
☐ Equine Morbillivirus
☐ Lassa fever virus
☐ Marburg virus
☐ Rift Valley fever virus
☐ South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
☐ Tick-borne encephalitis complex viruses
☐ Variola major virus (Smallpox virus)
☐ Venezuelan Equine Encephalitis virus
☐ Viruses causing Hantavirus pulmonary syndrome
☐ Yellow fever virus

BACTERIA

- ☐ Bacillus anthracis
☐ Brucella abortus, B. melitensis, B. suis
☐ Burkholderia (Pseudomonas) mallei
☐ Burkholderia (Pseudomonas) pseudomallei
☐ Clostridium botulinum
☐ Francisella tularensis (Type A=RG 3, BL 3), Type B=RG 3, BL 2)
☐ Yersinia pestis

RICKETTSIAE

- ☐ Coxiella burnetii
☐ Rickettsia prowazekii
☐ Rickettsia rickettsii

FUNGI

- ☐ Coccidioides immitis

TOXINS

- ☐ Abrin
☐ Aflatoxins
☐ Botulinum toxins
☐ Clostridium perfringens epsilon toxin
☐ Conotoxins
☐ Diacetoxyscirpenol
☐ Ricin
☐ Saxitoxin
☐ Shigatoxin
☐ Staphylococcal enterotoxins
☐ Tetrodotoxin
☐ T-2 toxin

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

TESTS / PROCEDURES PERFORMED

2. Do you perform the following tests/procedures?

DIAGNOSTIC IMMUNOLOGY

| | YES | NO |
|--|--------------------------|--------------------------|
| 1. Syphilis | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Alpha-1 Antitrypsin | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Alpha-Fetoprotein (Tumor Marker) | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Antinuclear Antibody | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Antistreptolysin O, Quantitative | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Anti-human Immunodeficiency Virus (HIV AB) | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Complement C3 | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Complement C4 | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Hepatitis Markers (HBsAg, AntiHBc, HbeAg, AntiHAV, AntiHCV) | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Ig A | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Ig G | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Ig E | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Ig M | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Infectious Mononucleosis | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Rheumatoid Factor | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Rubella | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Chlamydia (IF or EIA/NAP) | <input type="checkbox"/> | <input type="checkbox"/> |
| 18. PSA | <input type="checkbox"/> | <input type="checkbox"/> |
| 19. CEA | <input type="checkbox"/> | <input type="checkbox"/> |
| 20. H. pylori Antibody | <input type="checkbox"/> | <input type="checkbox"/> |
| 21. Other: _____ | <input type="checkbox"/> | <input type="checkbox"/> |

HEMATOLOGY

| | | |
|-----------------------------------|--------------------------|--------------------------|
| 1. Hbg | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Hct | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. WBC | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. RBC | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Blood Cell ID (Stained Slides) | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Automated Differential | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Pro Time | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. APTT | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Fibrinogen | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Platelet Count | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Semen Analysis/Counts | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Fecal Occult Blood | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. ESR | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Other: _____ | <input type="checkbox"/> | <input type="checkbox"/> |

* Methods that detect viral antigens employing either direct antigen, culture techniques or PCR.

* VIROLOGY

| | YES | NO |
|---------------------|--------------------------|--------------------------|
| 1. Herpes Simplex | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Chlamydia | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Cytomegalovirus | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Epstein-Barr | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. RSV | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Influenza A | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Influenza B | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Varicella-Zoster | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Rubella | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Rubeola | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Adenovirus | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Rotavirus | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Other: _____ | <input type="checkbox"/> | <input type="checkbox"/> |

URINALYSIS

| | | |
|----------------------------|--------------------------|--------------------------|
| 1. Specific Gravity | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Reagent Strip | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Reagent Strip-Automated | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Microscopic | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Urine Pregnancy | <input type="checkbox"/> | <input type="checkbox"/> |

TOXICOLOGY

| | | |
|--|--------------------------|--------------------------|
| 1. Alcohol (Blood) | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Blood Lead | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Carbamazepine | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Digoxin | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Ethosuximide | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Gentamicin | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Lithium | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Phenobarbital | <input type="checkbox"/> | <input type="checkbox"/> |
| 9. Phenytoin | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Primidone | <input type="checkbox"/> | <input type="checkbox"/> |
| 11. Procainamide (and Metabolite) | <input type="checkbox"/> | <input type="checkbox"/> |
| 12. Quinidine | <input type="checkbox"/> | <input type="checkbox"/> |
| 13. Theophylline | <input type="checkbox"/> | <input type="checkbox"/> |
| 14. Tobramycin | <input type="checkbox"/> | <input type="checkbox"/> |
| 15. Valproic Acid | <input type="checkbox"/> | <input type="checkbox"/> |
| 16. Erythrocyte Protoporphyrin | <input type="checkbox"/> | <input type="checkbox"/> |
| 17. Drugs of Abuse in Urine (Specify): _____ | <input type="checkbox"/> | <input type="checkbox"/> |

18. Other: _____ ☐ ☐

IMMUNOHEMATOLOGY

| | | |
|---|--------------------------|--------------------------|
| 1. Group and Type | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Unexpected Antibody Detection | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Antibody Identification | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Direct Antiglobulin | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Compatibility Testing (Licensed Blood Banks Only) | <input type="checkbox"/> | <input type="checkbox"/> |

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

TESTS / PROCEDURES PERFORMED, CONTINUED

Hospitals Only-Check (X) all in-house laboratory testing sites outside the main lab; list tests performed.

LOCATION

TESTS PERFORMED AT SITE

| | | | | | |
|---|-------|-------|-------|-------|-------|
| 1. <input type="checkbox"/> E.R. | _____ | _____ | _____ | _____ | _____ |
| 2. <input type="checkbox"/> O.R. | _____ | _____ | _____ | _____ | _____ |
| 3. <input type="checkbox"/> Recovery Room | _____ | _____ | _____ | _____ | _____ |
| 4. <input type="checkbox"/> ICU | _____ | _____ | _____ | _____ | _____ |
| 5. <input type="checkbox"/> CCU | _____ | _____ | _____ | _____ | _____ |
| 6. <input type="checkbox"/> Radiology | _____ | _____ | _____ | _____ | _____ |
| 7. <input type="checkbox"/> O. P. Clinic | _____ | _____ | _____ | _____ | _____ |
| 8. <input type="checkbox"/> Other (Specify) | _____ | _____ | _____ | _____ | _____ |
| _____ | _____ | _____ | _____ | _____ | _____ |

1. Check (X) all tests which are currently performed in your laboratory?

ROUTINE CHEMISTRY

| | | |
|---|---|---|
| <input type="checkbox"/> AST/SGOT | <input type="checkbox"/> Cholesterol, Total | <input type="checkbox"/> LDH Isoenzymes |
| <input type="checkbox"/> ALT/SGPT | <input type="checkbox"/> Cholesterol, HDL | <input type="checkbox"/> Magnesium |
| <input type="checkbox"/> Albumin | <input type="checkbox"/> Creatinine | <input type="checkbox"/> Potassium |
| <input type="checkbox"/> Amylase | <input type="checkbox"/> Creatine Kinase | <input type="checkbox"/> Sodium |
| <input type="checkbox"/> Alkaline Phosphatase | <input type="checkbox"/> Creatine Kinase, Isoenzymes | <input type="checkbox"/> Total Protein |
| <input type="checkbox"/> Bilirubin, Total | <input type="checkbox"/> Glucose (Excluding Waived Devices) | <input type="checkbox"/> Triglycerides |
| <input type="checkbox"/> Calcium, Total | <input type="checkbox"/> Iron, Total | <input type="checkbox"/> Urea Nitrogen |
| <input type="checkbox"/> Chloride | <input type="checkbox"/> LDH | <input type="checkbox"/> Uric Acid |
| <input type="checkbox"/> Other Tests Performed: _____ | | |

☐ Capillary Whole Blood Reagent Strip Cholesterol
(Specify Manufacturer and/or Instrument): _____

☐ Capillary Whole Blood Reagent Strip Glucose
(Specify Manufacturer and/or Instrument): _____

☐ Other Capillary Whole Blood Procedures
(Specify Test, Manufacturer and/or Instrument): _____

BLOOD GASES

| | | |
|-----------------------------|--|---|
| <input type="checkbox"/> pH | <input type="checkbox"/> PO ₂ | <input type="checkbox"/> PCO ₂ |
|-----------------------------|--|---|

ENDOCRINOLOGY

| | | |
|---|---|--|
| <input type="checkbox"/> Cortisol | <input type="checkbox"/> Human Chorionic Gonadotropin (performed on serum) | <input type="checkbox"/> Triiodothyronine |
| <input type="checkbox"/> Free Thyroxine | <input type="checkbox"/> T ₃ Uptake | <input type="checkbox"/> Thyroid Stimulating Hormone (TSH) |
| <input type="checkbox"/> Thyroxine | | |
| <input type="checkbox"/> Other Tests Performed: _____ | | |

2. Indicate the location of primary and back-up blood gas instruments. Include back-up instrument only if proficiency testing specimens are desired. Proficiency testing of back-up instrument is not required.

| Location of Blood Gas Instruments | Instrument | | Proficiency Test | |
|--------------------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| | Primary | Back | State | CAP |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| _____ | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

PHYSICAL PLANT

1. Location of Laboratory:
- ☐ Store ☐ Residence ☐ Hospital ☐ Professional Building
- ☐ Other, Specify: _____
2. Are quarters shared with any other enterprise?
- ☐ Yes ☐ No
- a. If yes, specify: _____
3. Does laboratory have private entrance and exit?
- ☐ Yes ☐ No

EQUIPMENT

List below or by attachment all major equipment now in use, including makes, models or types, sizes or capacity, age and current condition. Include microbiological safety cabinets, giving name of manufacturer and model. Licensure approval for microbacteriology and mycology is contingent upon availability of microbiological safety cabinet which meets the standards of NSF-49. List only changes or new equipment acquired since the last application was filed.

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

APPLICATION FOR A CLINICAL LABORATORY LICENSE, Continued

Please respond to the following:

A. Contracts or Agreements:

The laboratory has oral or written contracts or agreements with other laboratories, delivery services for transmission of specimens, business agents or independent sales representatives, including rental, leasing or other agreements with physicians, nursing homes, owners of professional building or other health care facilities.

☐ Yes

☐ No

B. Laboratory Charges (Provide copies of ALL current fee schedules and, if applicable, descriptions of all "pricing arrangements."):

☐ Yes

☐ No

1. The laboratory has "pricing arrangements."

☐ Yes

☐ No

2. The laboratory has casual, formal or charitable "courtesy" policies, deductions or "pricing arrangements."

☐ Yes

☐ No

3. The laboratory has a "direct patient billing" fee schedule.

☐ Yes

☐ No

4. The laboratory has a single professional** fee schedule.

☐ Yes

☐ No

5. The laboratory has two or more different professional fee schedules.

☐ Yes

☐ No

* As used here, "pricing arrangement" refers to any agreements (for example, discounts, individualized profiles, complimentary supplies or services, etc.) which would effectively modify the charges listed in the fee schedules.

** As used here, "professional" refers to nursing homes, other laboratories, hospitals, medical groups, clinics, individual physicians and third-party carriers (Medicare, Medicaid, Blue Cross, etc.).

We the undersigned certify that all the information given on this application and on the accompanying attachments is true, correct and complete as of this date and that notification, by certified mail, of any change(s) will be made within 14 days of such change(s). We further certify that testing will not be performed until all applicable State and Federal certificates, licenses and required approvals have been obtained.

Please number all attachments consecutively and record the number of pages attached to this application.

Number of pages attached:

Signature of Director

Date

Signature of Co-Director

Date

Signature of Owner

Date

Signature of Owner

Date

Signature of Owner

Date

Sworn to before me this _____ day of _____, 20_____

Notary Public: _____